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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,705

02/15/2005

David Varon

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09/20/2005

NATH & ASSOCIATES

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EXAMINER

DIRAMIO, JACQUELINE A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/511,705	Applicant(s) VARON, DAVID	
	Examiner Jacqueline DiRamio	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-61 is/are pending in the application.
- 4a) Of the above claim(s) 40-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 26 – 39 in the reply filed on August 30, 2005 is acknowledged.

Claims 40 – 61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the term "said magnification," which lacks antecedent basis.

Claim 38 recites the term "affinity microbeads," which is vague and indefinite because it is unclear what exactly constitutes an "affinity microbead" and the specification (pg 9) fails to teach the exact meaning of this term.

Claim 39 recites the term "immunobeads," which is vague and indefinite because it is unclear what exactly constitutes an "immunobead" and the specification (pg 9) fails to teach the exact meaning of this term.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26 – 33 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Berliner (US 2002/0001402).

The Berliner reference teaches a method for generating a profile of particulate components of a body fluid sample, wherein the profile can be used to detect or diagnose a clinical condition, such as an inflammatory response in an individual (see paragraph [0082]). The method comprises mixing a fluid sample with a reagent that contains proteins or interacting molecules that can bind to molecules (analytes) found in the sample, creating a binding couple with the particulate components. The reagent is coated on a solid substrate, particularly a slide, wherein the reagent mixes with the fluid sample thus creating a thin layer of the particulates binding with the precoated reagent. The adherence of the particulates to the solid substrate is viewed and an optical image is obtained using an imaging device, such as a camera. The image is analyzed and the particulates are evaluated for their adherence to the substrate through their interaction with the coated reagents (i.e. proteins or antibodies) and further, the particulates are

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analyzed for additional parameters (see paragraphs [0029], [0091], [0096], [0098], [0104]-[0107], and [0138]).

With respect to Applicant's claim 27, Berliner teaches the analyte in the form of specific cell surface molecules, wherein more than one recognition site is available and the interacting molecule (capturing agent) precoated on the substrate is preferably in the form of an antibody, which comprises at least two capturing moieties. Therefore, the association between the surface molecules (analyte) and the capturing moiety of the antibody forms a binding couple, which adheres to the surface of the substrate (see paragraphs [0227]-[0230]).

With respect to Applicant's claim 28, the parameters evaluated for the adhered particulates include: particulates' count, aggregation (size), degree of aggregation (size distribution), aggregate composition (shape distribution), concentration, shape, etc. (see paragraphs [0104] and [0105] in particular).

With respect to Applicant's claims 29 and 30, the image acquired of the adhered particulates is a magnified image, preferably obtained from a light microscope (see paragraph [0096]).

With respect to Applicant's claims 31 – 33, the analyte studied by Berliner is a particle in the form of a cell, which presents specific cell surface molecules, which are capable of interacting with the molecules (capturing agents) adhered to the surface of the substrate. The cell surface molecules thus contain more than one copy of an epitope or recognition site which can associate with the interacting molecules (capturing agent). The interacting molecules are preferably in the form of antibodies, which

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interact with an epitope(s) (recognition site) of the specific cell surface molecules (antigens) (see Example 7 and Table 3 on pg. 14 in particular).

With respect to Applicant's claim 39, Berliner teaches the particulates that adhere to the substrate through binding can be in the form of a thin layer or monolayer of cells (see paragraphs [0138], [0251] and Figures 17a, 17b and 22a in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berliner (US 2002/0001402) in view of Kelso (US 2003/0129296).

The Berliner reference, which has been discussed in the 102(e) rejection above, fails to teach that the reagent comprises microbeads having a sensing interface, wherein the sensing interface carries capturing moieties.

Kelso teaches film-immobilized capture particles wherein particles (microbeads) are coated with capture reagents (sensing interface), which are molecules attached to the surface of the particles that are capable of binding to the target molecule. The capture reagents include antibodies (monoclonal or polyclonal), receptors, proteins, nucleic acids, polymers, etc. (see paragraphs [0030]-[0032]). Kelso teaches the capture particles for forming a microarray wherein at least two unique capture particle species (capturing moieties) are attached to the particles' surface, which can represent the same capture particles species or different capture particle species (see claims 1,2 and 16 in particular). The use of the particles (microbeads) pre-coated with specific capture reagents to form the capture agents allows for many points of attachment for the target molecules, which increases coupling efficiency and assay sensitivity (see paragraphs [0004], [0005] and [0055]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine with the method of Berliner the use of particles coated with the capture reagents (sensing interface) as taught by Kelso because Kelso teaches the benefit of using particles pre-coated with specific capture reagents to form the capture agents because they allow for many points of attachment for the target molecules, which increases coupling efficiency and assay sensitivity.

With respect to Applicant's claims 37 and 38, the particles taught by Kelso can have a variety of capture reagents attached to their surface, the capture reagents are any molecule that are capable of binding to the target molecule, which would therefore, represent an "affinity" particle (microbead). Further, the capture reagents can be in the form of proteins, particularly receptors useful for detecting immune responses or immune complexes, which therefore, represent immunoparticles (beads) (see paragraphs [0032] and [0069]).

Conclusion

No claims are allowed.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Hubscher et al. (US 6,632,603) teach a non-captive substrate immunoassay wherein reagents containing a binding substance for a target analyte are mixed with a fluid sample containing the analyte and this mixture is then applied to a solid substrate. The solid substrate contains a certain pore size that captures any complexes that form between the binding substance and the analyte and permits uncomplexed substances to flow through the substrate's pores. The analytes that have complexed with the binding substances are detected through various detection methods known in the art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jackie DiRamio
Patent Examiner
Art Unit 1641



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09/14/05